114th MEETING OF THE NATIONAL CANCER ADVISORY BOARD

AD HOC SUBCOMMITTEE ON CONFIDENTIALITY

National Institutes of Health, Building 31C
Bethesda, Maryland
June 13, 2000

Discussion Summary

Background

The group's discussion focused on the issues raised and recommendations for practices suggested in the report *Confidentiality, Data Security and Cancer Research: Report of a Workshop* based on a National Cancer Institute (NCI)-sponsored meeting that was held December 1–2, 1999. The workshop and report are part of a proactive effort by the NCI to develop a balanced approach to this important issue and to stimulate discussion of ways to ensure the protection of confidentiality without placing unnecessary restrictions on research. The report is now being reviewed widely. The report has been disseminated for review to Cooperative Group Chairs, Cancer Center Directors, the Cancer Leadership Council, the Cancer Genetics Network, the Director's Consumer Liaison Group, the Epidemiology and Genetics Research Program, Specialized Programs of Research Excellence, the Early Detection Research Network, the Board of Scientific Advisors, the President's Cancer Panel, and the Surveillance, Epidemiology and End-Results Program. The draft report also is on the NCI Web Site. The comment period will last for at least 4–5 months. Dr. Li and Ms. McCabe encouraged meeting participants to distribute the report to their colleagues and organization members in an effort to generate additional comments.

The report addresses needs, principles, and practices for ensuring confidentiality of research information, since this is a topic that is under the purview of the NCI.

Discussion

Dr. Li and Ms. McCabe asked the group to consider how the recommendations from the report should be handled and whether they should become NCI policy. The following points were raised in discussion:

- Several participants stressed the educational value of the report since it presents a clear set of practices for ensuring confidentiality. One participant commented that it was very helpful to have all of this material in one place; she planned to integrate the report into training programs. No one was aware of in-depth education and/or training modules on confidentiality; it is covered briefly in courses in different curricula, but not in detail as it is in this report.

- The group discussed the potential role of the "security officer" or "privacy officer" who would oversee confidentiality practices and ensure that they were followed. Most agreed that the role should emphasize education rather than "policing" to avoid a chilling effect on research. The privacy officer could function like a safety officer at an institution, issuing warnings when mistakes are made. It was noted, however, that the public will demand some form of consequence for intentional violations of confidentiality.
- One participant noted that regulation would not be necessary if consensus could be reached among experts in the field to adopt the principles and practices, much like it is not necessary to have a regulation on "cheating" since there is unanimity on not "cheating" as a principle. It would be best if the report recommendations were formally adopted but not mandated.

Dr. Li asked the group to think beyond the general principles in the report and consider whether implementation of the recommendations in practice would present problems for institutions. Would they be overwhelming? What infrastructure might be needed and what burdens would this impose? The following points were raised:

- The group noted that the principles are already in place, so the recommendations do not impose entirely new requirements.
- One participant noted that space requirements might be the only burden since one of the key elements is maintaining study records and clinical medical records in separate places.
- The group discussed the use of data for medical and study purposes and noted that some data will be needed in both places.
- One participant stated that files are not maintained in separate locations while patients are receiving inpatient care; that would be too cumbersome when a patient is receiving active treatment. Upon discharge, she stated that data managers abstract the appropriate data and this excerpted subset then is treated confidentially.
- One participant noted that research institutions do not control all access to data. For example, auditors have access to confidential information and so institutions cannot guarantee that they will not breach confidentiality.
- The group discussed some specific issues in confidentiality, such as how the practices would affect transfer of data among states and protecting the confidentiality of family members if a patient speaks to the media.
- One participant stated that the benefit of being proactive, and perhaps avoiding the imposition of regulations by Congress or another political body, outweighed any potential burden. He noted that this proactive approach was in researchers' best interest and is the researchers' responsibility.

Recommendations

The group did not reach consensus-based conclusions or develop formal recommendations. The following ideas received considerable support:

- Use the report as an educational tool and develop curriculum modules to address the principles and practices.
- Disseminate the draft report widely and encourage comments; include the Society for Clinical Trials and other professional organizations as well as advocacy groups.
- Make sure recommendations are congruent with those of accreditation bodies and other professional organizations.
- Incorporate the principles and practices into manuals for clinical trials. Ask grantees to test the practices and provide feedback on their experience, including any burdens they experience.
- At the conclusion of the review and comment period, assess how many institutions have taken steps to address some or all of the recommendations and gather information on their experiences.

6/14/00
Date

Dr. Frederick Li, Chairperson

6-20-00
Date

Ms. Mary McCabe, Executive Secetary